REMARKS

This reply and accompanying amendments, filed in response to the Office Action March 14, 2008, fully address all the issues raised in the Action. Favorable reconsideration of the application is respectfully requested.

Upon entry of the amendments, claims 1-4 are all the claims pending in the application and claim 1 is amended to further clearly point out the claimed feature of the invention. The currently presented claim 1 recites, among others, the specific weight ratio between polyoxyethylene : natural gum. Support for the amendment to claim 1 may be found by the disclosure of the specification, for example Examples 1-12 in the specification. No new matter is introduced and entry of the amendment is respectfully requested.

Applicants thank the Examiner for considering and returning the initialed copy of the US/PB/08 form submitted December 7, 2007.

Rejection under 35 U.S.C. §103(a)

In the Office Action, claims 1-4 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Sanghvi *et al.* (U.S. Pat. Publication No. 2007/0109891) in view of Shell *et al.* (U.S. Pat. No. 6340475).

The Office asserts that Applicant's arguments have been fully considered but are not persuasive.

Applicants respectfully disagree to the Office's assertions. In particular, Applicants respectfully submit again that, Sanghvi does not teach the incorporation of polyethylene oxide. In this regard, Applicants draw the Office's attention to the fact that Applicants did not state that

Sanghvi contains negative recitation for excluding polyethylene oxide. Furthermore, regarding Shell, Applicants respectfully submit again that Shell does not teach the specific ratio of the combination of polyethylene oxide and a gum such as xanthan gum.

The Combination of a polyoxyethylene oxide and a natural gum, in a controlled release formulation of metformin, which is suitable for oral administration, at a weight ratio of 0.27:1 to 1.6:1 is not taught or suggested by Sanghvi or Shell, alone or in combination. In addition, Applicant respectfully submit that compositions containing the combination of polyoxyetheylene and a natural gum at a such ratio exhibit unexpected remarkable effects.

One of the inventors conducted the following tests in order to demonstrate the remarkable effects of the currently claimed inventive composition having the specific weight ratio of a polyethylene oxide ("PEO"):a natural gum (i.e., 0.27:1 to 1.6:1).

<Preparation of comparative compositions>

A tablet having each of the compositions listed in Table 1 was prepared by repeating the procedure of Example 1.

Table 1

Ingredients		Content(wt%)			
		Comparative (i)	Comparative (ii)	Comparative (iii)	Comparative (iv)
Granule forming part	Metformin·HCl	50	50	50	50
	Polyethylene oxide (Polyox®WSR, M.W. 5,000,000)	2.5	1.4	9.6	10
Mixture part	Polyvinylacetate/ Polyvinyl pyrrolidone mixture	20	20	20	20
	Wax	13	13	13	13
	Xanthan gum	12.5	13.6	5.4	5
	Silicon dioxide	1	1	1	1
	Magnesium stearate	1	1	1	1
Total		100	100	100	100
PEO:natural gum		0.2:1	0.1:1	1.8:1	2.0:1

<*In vitro* release-tests for the tablets prepared in Comparative Examples (i) to (iv) and Example 1>

In vitro release-tests were conducted for the tablets prepared in Comparative Examples (i) to (iv) above and Example 1 described in the specification by repeating the method of Test Example 1 described in the specification.

As can be seen from Figs A and B below, both of the formulations of Comparative Examples (i) and (ii) having weight ratios below 0.27:1 and those of Comparative Examples (iii) and (iv) having weight ratios above 1.6:1 exhibit an initial burst release of metformin,

which may cause gastrointestinal adverse effects, as compared in the inventive formulation of Example 1.

Figure A

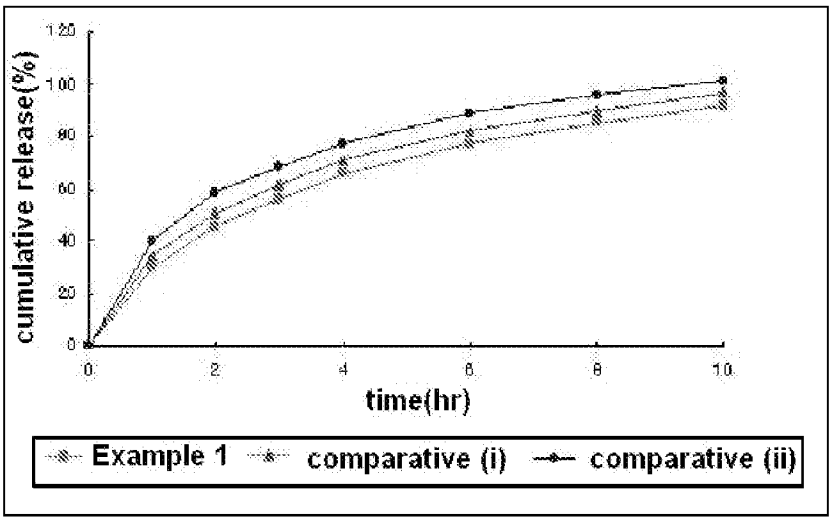
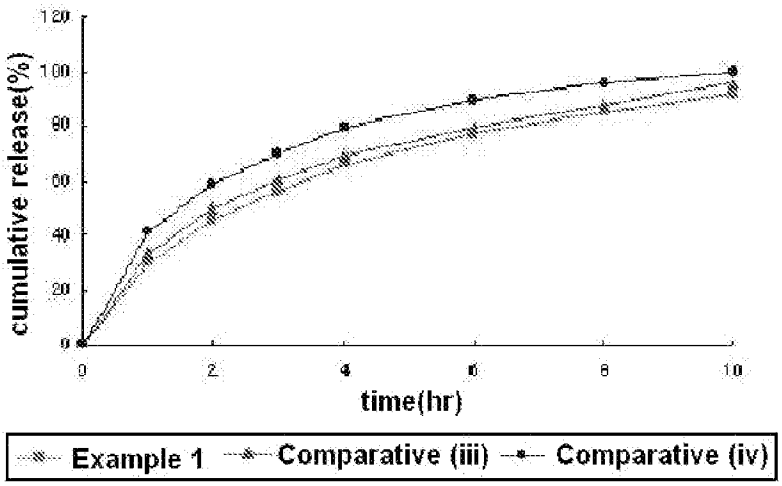


Figure B



The remarkable effect obtained in the range of 0.27:1 to 1.6:1 as a PEO:a natural gum can be more clearly recognized in view of the comparison of $t_{90\%}$ (time to 90% drug release) between the formulations of Examples 1 to 12, and those of Comparative Examples 1, 2 and (i) to (iv).

Table 2

	Weight ratio (PEO:natural gum)	$t_{90\%}$
Example 1	0.8:1	>10
Example 2	0.5:1	10
Example 3	0.5:1	10
Example 4	0.5:1	9
Example 5	1:1	>10
Example 6	1:1	10
Example 7	0.8:1	>10
Example 8	0.8:1	>10
Example 9	1.6:1	10
Example 10	0.44:1	10
Example 11	0.63:1	>10
Example 12	0.27:1	>10
Comparative Example 1	0:1	6
Comparative Example 2	1:0	5
Comparative Example (i)	0.2:1	8
Comparative Example (ii)	0.1:1	6
Comparative Example (iii)	1.8:1	8
Comparative Example (iv)	2.0:1	6

* Examples 1 to 12 and Comparative Examples 1 and 2 are described in the specification.

As can be seen from Table 2 above, the inventive formulations having the weight ratio of 0.27:1 to 1.6:1 show desired t_{90}% values ranging from approximately 9 to 10 hours, while the t_{90}% values of the comparative formulations are not more than 8 hours.

Therefore, it is clear that the selection of the range of 0.27:1 to 1.6:1 as the weight ratio of a PEO : a natural gum leads to unexpected remarkable increase in the controlled release effect of the formulation.

The above tests and results are also submitted in the accompanying Rule 1.132 Declaration, which is executed by Mr. Jong-Soo Woo.

In conclusion, Applicants respectfully submit that the rejection under 35 U.S.C. §103 is not sustainable and withdrawal is respectfully requested.

CONCLUSION

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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